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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,642

04/16/2007

Ana Gomez-Rodriguez

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4902

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05/15/2009

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B482

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RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

05/15/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/587,642	<b>Applicant(s)</b> GOMEZ-RODRIGUEZ ET AL.	
	<b>Examiner</b> JaNa Hines	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 and 46-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9 and 14-21 are drawn to a process for generating and detecting recombinant DNA sequences in prokaryotes wherein the prokaryotic cell is transiently or permanently deficient in the mismatch repair system.

Group II, claim(s) 10-13 are drawn to a process for generating and detecting recombinant DNA sequences in prokaryotes wherein the donor DNA molecule is the *B. subtilis* plasmid pMIX91 comprising the spec<sup>R</sup> marker and the phleo<sup>R</sup> marker or the *B. subtilis* plasmid pMIX101 comprising the tc<sup>R</sup> marker.

Group III, claim 42 is drawn to *Bacillus subtilis* plasmid pMIX91 which comprising the spec<sup>R</sup> marker and the phleo<sup>R</sup> marker and the restriction sites Scal, PpuMI and EcoO1091 for inserting a foreign DNA sequence.

Group IV, claim 43 is drawn to *Bacillus subtilis* plasmid pMIX101 which comprising the tc<sup>R</sup> marker sequence and the restriction sites XhoI and PstI for inserting a foreign DNA sequence.

Group V, claim 46 is drawn to a kit comprising a first container of *E. coli* strain AB1157 or the *E. coli* strain MXP1 or the *E. coli* strain DB10, a second container which comprising *E. coli* strain AB1157 containing plasmid pACYC184 or cell of DHB10 containing plasmid pMIX100 and a third container comprising cells of *B. subtilis* DSM 1715 containing plasmid pMIX91 or *B. subtilis* strain DSM17159 containing pMIX101.

Group VI, claim 47 is drawn to a kit comprising a first container which comprises cells of *E. coli* strain AB1157 or the *E. coli* strain MXP1 or the *E. coli* strain DHB10, a second container comprising DNA of plasmid pACYC184 or plasmid pMIX100 and a third container comprising DNA of plasmid pMIX91 or plasmid pMIX101.

Group VII, claim 48 is drawn to a process for producing a hybrid gene and/or protein encoded by a hybrid gene in a prokaryotic cell.

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2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each group has a different and distinct ability, unrelated to the other groups. The *Bacillus subtilis* plasmid pMIX101 which comprising the tc<sup>R</sup> marker sequence and the restriction sites XhoI and PstI of group IV, can be used with other methods and can be used separately from the other products. For instance, the *Bacillus subtilis* plasmid pMIX101 not need to be used with a process for generating and detecting recombinant DNA sequences in prokaryotes wherein the donor DNA molecule is the *B. subtilis* plasmid pMIX91 comprising the spec<sup>R</sup> marker and the phleo<sup>R</sup> marker or the *B. subtilis* plasmid pMIX101 comprising the tc<sup>R</sup> marker. Therefore, the plasmid's special technical feature is comprised within the product and its ability to be a *Bacillus subtilis* plasmid pMIX101 which comprising the tc<sup>R</sup> marker sequence and the restriction sites XhoI and PstI; therefore the groups lack the same or corresponding technical feature.

Groups I and II, is drawn to an unrelated inventions because it use, function and effect are patentably distinct in comparison to the other groups. Group I has a different special technical feature when compared to the claim of Group II; because the recited product is the special technical feature. These special technical features are comprised within their differences and their ability to have different final results. Accordingly, the groups lack a corresponding technical feature. Finally, groups V and VI are unrelated and do not share a special technical feature because each product has a separate and distinct purpose with separate and distinct final

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outcomes and different kits characterized by their inclusion of different components.

Therefore, there is no corresponding special technical feature between the groups I-VII.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JaNa Hines whose telephone number is (571)272-0859.

The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JaNa Hines/  
Examiner, Art Unit 1645

/Mark Navarro/  
Primary Examiner, Art Unit 1645

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